

CLAIMS:

We claim:

1. A method, comprising:
 - selecting a diverse group of sera, the diverse group of sera having different characteristics;
 - diluting each serum of the diverse group of sera with a plurality of different diluents;
 - obtaining information associated with a mass spectrum of each of the diluted sera from the diverse group of sera using an electrospray process;
 - generating a control model based at least in part on the spectrum obtained from the diverse group of sera;
 - diluting a test serum with a test diluent;
 - performing mass spectrometry on the test serum to obtain a test spectrum associated with the test serum;
 - mapping the test spectrum obtained from said performing to the control model;
 - determining whether the test spectrum obtained from said performing maps to the control model.
2. The method of claim 1, said generating further comprising:
 - selecting a cluster that contains the greatest number of vectors from the spectra to define the control model.
3. The method of claim 1, wherein said diluting each serum of the diverse group of sera includes diluting the sera with diluents having a predetermined diluent concentration, and said diluting a test serum with a test diluent includes diluting a test serum with a diluent having the same concentration as the diluent used to dilute each serum of the diverse group of sera.

4. The method of claim 1, wherein said diluting each serum of the diverse group of sera includes diluting the sera with diluents having a predetermined diluent concentration, and said diluting a test serum with a test diluent includes diluting a test serum with a diluent having a different concentration than the diluent used to dilute each serum of the diverse group of sera.
5. The method of claim 1, further comprising:
classifying a biological state from the spectrum based on a predetermined biological state model.
6. The method of claim 1, wherein if said determining determines that the spectrum does not map to the control model, and the diluent is a first diluent, the method further comprising:
repeating the steps of diluting, performing, mapping, and determining for a second diluent.
7. The method of claim 1, said selecting further comprising:
selecting at least two different sera from a pool of diverse sera, the pool of diverse sera consisting of: sera from healthy males, sera from healthy females, sera from males afflicted with a disease, sera from females afflicted with a disease, sera from persons of different races, and sera from people of different ages.
8. The method of claim 1, wherein said generating includes:
identifying at least one cluster in common to the sera of the diverse group of sera and the plurality of different diluent; and
selecting only one cluster as part of the control model.
9. The method of claim 1, wherein the obtaining information includes:
obtaining information on sera diluted with two different diluents, the diluents including at least acetonitrile and methanol.
10. The method of claim 1, wherein the test diluent is one of the plurality of different diluents.

11. The method of claim 1, wherein the test diluent is not one of the plurality of different diluents.
12. A method of quality assurance employing a control model generated based on mass spectra obtained from sera analyzed following an electrospray process, the spectra being associated with a plurality of different sera and a plurality of different diluents, comprising:
 - diluting a serum using a diluent;
 - ionizing the diluted serum using an electrospray ionization process;
 - performing mass spectrometry on the ionized diluted serum to obtain spectral data associated with the serum and the diluent; and
 - mapping the spectrum to the control model, said mapping being performed to determine if the serum and the diluent are suitable for further diagnostics.
13. The method of claim 12, further comprising:
 - determining that the serum and diluent are suitable for further diagnostics; and
 - submitting the spectral data to a biological model to determine if the biological sample exhibits a particular biological state.
14. The method of claim 13, wherein diluting a serum includes diluting a serum using one of acetonitrile and methanol.

15. A method, comprising:

diluting at least two sera of a diverse group of sera with a diluent having a plurality of different concentrations to yield a plurality of diluted sera samples, the plurality of diluted sera samples having different concentrations of serum to diluent;

ionizing at least some of the plurality of diluted sera samples using an electrospray ionization process to yield a plurality of ionized diluted sera;

obtaining spectral data associated with the ionized diluted sera;

generating a control model associated with the diluted sera samples;

diluting a test serum with a diluent to yield a diluted test serum;

ionizing the diluted test serum using the electrospray ionization process to yield an ionized diluted test serum;

obtaining spectral data associated with the diluted test serum;

mapping the spectral data associated with the diluted test serum to the control model; and

determining whether the diluted test serum produces a spectrum within a predetermined tolerance.

16. The method of claim 15, wherein said diluting at least two of a diverse group of sera includes diluting a diverse group of sera using at least one of acetonitrile and methanol.

17. The method of claim 15, wherein said diluting at least two sera of a diverse group sera includes creating a plurality of dilutions of the at least two of the plurality of diverse group of sera with a diluent having a plurality of concentrations.

18. The method of claim 15, wherein said diluting at least two sera of a diverse group of sera includes creating a plurality of dilutions of the at least two of the plurality of diverse group of sera with a diluent having a plurality of concentrations, the concentrations ranging between 1:250 to 1:1000.

19. The method of claim 15, wherein said generating the control model includes:
determining the location of at least one cluster in n-dimensional space; and
selecting a cluster having the greatest number of vectors within the cluster to define the control model.
20. The method of claim 15, wherein said diluting the test serum includes diluting the test serum with a known diluent.
21. The method of claim 15, wherein said diluting the test serum with a diluent includes diluting the test serum with the same diluent used to dilute the at least two sera of a diverse group of sera.
22. The method of claim 15, wherein said diluting the test serum with a diluent includes diluting the test serum with a different diluent than the diluent used to dilute the at least two sera of a diverse group of sera.
23. The method of claim 15, wherein the test diluent is one of the plurality of different diluents.

24. A method, comprising:

diluting a first serum and a second serum, the first serum having different properties from the second serum, the first serum and the second serum being diluted with a diluent to produce a diluted first serum and a diluted second serum;

ionizing the diluted first serum using an electrospray ionization process;

obtaining spectral data associated with the diluted first serum;

ionizing the diluted second serum using an electrospray ionization process;

obtaining spectral data associated with the diluted second serum;

mapping the spectral information obtained from the diluted first serum and the diluted second serum into n-dimensional space;

generating a control model based on said mapping, the control model being based on the diluted first serum and the diluted second serum;

diluting a test serum with a diluent to yield a diluted test serum;

ionizing the diluted test serum using the electrospray ionization process to yield an ionized diluted test serum;

obtaining spectral data associated with the diluted test serum;

mapping the spectral data associated with the diluted test serum to the control model; and

determining whether the diluted test serum produces a spectrum that satisfies predetermined criteria.

25. The method of claim 24, wherein said ionizing the diluted first serum and ionizing the diluted second serum are ionized by the same electrospray ionization process.

26. The method of claim 24, wherein said determining whether the diluted test serum produces a spectrum that satisfies predetermined criteria includes:

identifying whether the spectrum is within one of a first hypervolume and a first volume such that one of the first volume and the first hypervolume excludes at least 90% of one of a second hypervolume and a second volume, the one of a second hypervolume and a second volume being the total volume of hypervolume of an n-dimensional space.